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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,613	07/14/2008	John V. Frangioni	BIDM-P01-015	3557

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ROPES & GRAY LLP
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EXAMINER	
BOOSALIS, FANI POLYZOS	

ART UNIT	PAPER NUMBER
2884	

MAIL DATE	DELIVERY MODE
03/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,613	FRANGIONI ET AL.	
	Examiner	Art Unit	
	Faye Boosalis	2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date *5/06, 6/06, 5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

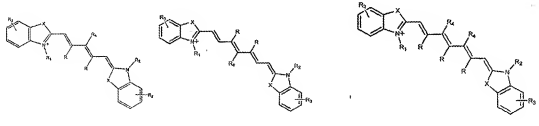
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Licha et al (US 6,319,488 B1).

Regarding claims 1-3, Licha discloses an imaging agent comprising a serum albumin protein (colloids from protein such as albumins, collagen, gelatin, etc) covalently conjugated or admixed with one or more infrared or near-infrared fluorescent substances (col. 2, lines 20 - col. 3, line 4).

Regarding claims 4 and 11, Licha discloses wherein the imaging agent comprises a fluorescent substance having a structure of formula (I) or formula (II) or formula (III):



wherein, as valence and stability permit, x represents $C(R)_2$, S, Se, O or NR_5 (col. 5, lines 26-35); R represents H or lower alkyl, or two occurrences of R, taken together, from a ring together with the carbon atoms through which they are connected (See general formulas I, II or III – col. 3, lines 66-col. 5, line 25); R_1 and R_2 represent, independently, substituted or unsubstituted lower alkyl, lower alkenyl, cycloalkyl, cycloalkylalkyl, aryl, or aralkyl, e.g., optionally substituted by sulfate, phosphate, sulfonate, phosphonate, halogn, hydroxyl, amino, cyano, nitro, carboxylic acid, amide, etc., or a pharmaceutically acceptable salt thereof (col. 3, lines 65-col. 4, line 52); R_3 represents, independently for each occurrence, one or more substituents to the ring to which it is attached, such as a fused ring (e.g., a benzo ring) (See formulas I, II or III) (col. 4), sulfate, phosphate, sulfonate, phosphonate, halogen, lower alkyl, hydroxyl, amino, cyano, nitro, carboxylic acid, amide, etc., or a pharmaceutically accepted salt thereof (col. 3, lines 65-col. 4, line 52); R_4 (E^1 or E^2) represent H, halogen, or a substituted or unsubstituted either or thioether or phenol or thiophenol (col. 3, lines 65-col. 4, line 67); and R_5 represents, independently for each occurrence, substituted or unsubstituted lower alkyl, cycloalkyl cycloalkylalkyl, aryl, or aralkyl, e.g., optionally substituted by sulfate, phosphate, sulfonate, phosphonate, halogen, hydroxyl amino, cyano, nitro, carboxylic acid, amide, etc., or a pharmaceutically acceptable salt thereof (col. 4, lines 65-66).

Regarding claims 5 and 12, Licha discloses a pharmaceutical preparation comprising an imaging agent of claim 1 or 2, and a pharmaceutically acceptable excipient (col. 5, lines 52-54).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6-10, 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licha et al (US 6,319,488 B1).

Regarding claims 6, 10, 13 and 16, Licha discloses wherein the imaging agent comprises a fluorescent substance selected from polymethine dyes. Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to use dyes selected from indocyanine green, IRDye78, IRDye80, IRDye38, IRDye40, IRDye41, IRDye700, IRDye800CW, Cy7, IR-786, DRAQ5NO, or an analog thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 7, 14, Licha discloses wherein the serum albumin protein is a human serum albumin protein (col. 10, lines 1-3).

Regarding claims 8-9 and 15, Licha discloses the imaging agent comprising a serum albumin protein (colloids from protein such as albumins, collagen, gelatin, etc)

covalently conjugated or admixed with one or more infrared or near-infrared fluorescent substances (col. 2, lines 20 - col. 3, line 4). Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to use noncolloidal serum albumin protein, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claim 17, Licha discloses a method of imaging either the lymphatic or circulatory system of an animal or any portion thereof (col. 10, lines 1-3), comprising: introducing the imaging agents, as claimed supra, into the animal (i.e. nude mouse with an LS174T tumor) (col. 2, lines 14-16); exposing the animal or portions thereof to light; and detecting an emission wavelength of the imaging agent (col. 1, lines 36-43).

Regarding claim 18, Licha discloses a method of imaging the lymphatic system of an animal or any portion thereof (col. 10, lines 1-3), comprising: introducing a fluorophore into the animal (i.e. nude mouse with an LS174T tumor) (col. 2, lines 14-16); exposing the animal or portions thereof to light; and detecting an emission wavelength of the imaging agent (col. 1, lines 36-43).

Regarding claim 19, Licha discloses wherein the imaging agent comprises a fluorescent substance selected from polymethine dyes. Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to use dyes selected from indocyanine green, IRDye78, IRDye80, IRDye38, IRDye40, IRDye41, IRDye700, IRDye800CW, Cy7, IR-786, DRAQ5NO, or an analog thereof, since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claim 20, Licha discloses wherein the light comprises an excitation wavelength of the fluorescent substance (col. 2, lines 20-25).

Regarding claim 21, Licha discloses wherein an emission wavelength included generating an image from light detected in the near-infrared or infrared wavelength region (col. 2, lines 20-25 and 30-34).

Regarding claims 22-23 and 25, Licha discloses comprising a CCD camera generating color images of surrounding areas of injection site (i.e. tumor tissue) and in near-infrared or infrared wavelength regions (col. 6, lines 56-61).

Regarding claim 24, Licha discloses wherein detecting an emission wavelength includes imaging a site of the animal that is exposed by surgery or another medical procedure (i.e. vivo contrast medium and target tissue combination) (col. 6, lines 63-67).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Faye Boosalis whose telephone number is 571-272-2447. The examiner can normally be reached on Monday thru Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David P. Porta/
Supervisory Patent Examiner, Art Unit 2884

/FB/